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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,432	04/10/2001	Karen A. Ketchum	CL001013-CIP	8734

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CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,432	KETCHUM ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 4-5, 8-11 and 22-23, drawn to nucleic acid encoding a human transporter protein, a vector and a host cell in Paper No.: 6 (8/19/02) is acknowledged. Applicant has elected to cancel claims 1-3, 5-7 and 10-23 after amendments. Applicant has further elected the amino acid sequence of SEQ ID No: 2. In addition, Applicant has elected the nucleic acids that encode SEQ ID No: 2 such as, for example, SEQ ID No: 1. Claims 4, 8, 9 and 24-29 are pending.

Drawings

2. The drawings have been objected to by the draftsperson (see attached 948). Appropriate correction is required.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 28 are rejected as being indefinite because the claims recite recombinant methods for producing a polypeptide comprising insertion of the polynucleotide of claim 4 in a vector into a host cell. Claim 4(d) recites a polynucleotide consisting of "a nucleotide sequence that is completely complementary to a nucleotide sequence of (a)-(c)". It is not clear how the polynucleotide complements of claim 4(d) produce the polypeptide (SEQ ID NO: 2) disclosed in the instant application. A complement is a sequence of nucleotide bases in one strand of a DNA or RNA molecule that is exactly complementary (adenine-thymidine, adenine-uracil, or guanine-cytosine) to that on another single strand. Claim 29 is rejected insofar as it depends on claim 28.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4, 8, 9 and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are directed to a polypeptide comprising SEQ ID No: 2 encoded by the nucleotide of SEQ ID No: 1 and 3 belonging to an alleged human transporter protein. These claims are drawn to an invention with no apparent or disclosed patentable utility. The applicant claims that the protein of the invention is expressed in the breast and spleen based

presumably on BLAST hits. In addition, based on tissue screening panels Applicant is able to show expression in human whole liver (Figure 1). The only experimental data provided in Figure 1 is nucleotide sequence information and BLAST hits. There are no RNA or protein blots to indicate the expression profile. In addition, the instant application does not disclose the biological role of this protein or its significance. Novel biological molecules lack well-established utility and must undergo extensive experimentation.

The applicant claims that the human transporter protein sequence apparently encodes a 457 amino acid protein (Figure: 2) and contains structural features characteristic of transporter protein (Figure: 2). This is presumably because of sequence homology between the instant invention (human transporter protein sequence) and other transporter protein. However, the homology of a peptide is not a reliable indicator for the functional characteristics (see Scott et al. 1999). The Scott et al. reference based on the amino acid sequence homology it was predicted that the Pendred syndrome gene to be a sulfate transport protein. However, the results demonstrated that the protein was a chloride-iodide transporter protein (see abstract). Furthermore, since the specification does not disclose any methods or working examples that demonstrate the polynucleotide and polypeptide of the instant application exhibit activities similar to monocarboxylate transporter protein, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a transporter protein. Additionally, the specification of the instant application does not teach the skilled artisan which domains of transporter protein sequence are structurally related to other monocarboxylate transporter proteins. One skilled in the art would not know the utility and function of human transporter protein, even if it was a putative transporter protein because, as

discussed in the related art above and the specification of the instant application, neither the prior art nor the specification provides for the physiological significance of the claimed monocarboxylate transporter protein.

There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to nucleotides and peptides, which have a yet undetermined function or biological significance. Applicants have disclosed that they are in possession of polypeptide SEQ ID NO: 2 encoded by nucleotides of SEQ ID No: 1 or SEQ ID No: 3 (genomic sequence). In addition, Applicant also claims the expression in

the human breast and spleen (page: 16). However, there is no actual and specific significance which can be attributed to said polypeptides and the polynucleotides identified in the specification, except the prophetic recitation of potential uses, which include the use of this transporter protein and the nucleotides in screening assays, diagnosing a disease, raise antibodies, tissue markers, binding assays, etc. (pages: 26-62). For this reason, the instant invention is incomplete. Since, neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor, there is no immediately obvious patentable use for it. In addition, the instant specification does not disclose a "real-world" use for said polypeptides and polynucleotides, except the prophetic recitation of potential uses, which include possible biological and therapeutic uses. Also, there are no working examples that demonstrate any specific utility. Thus, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Therefore, since the peptide of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the composition comprising the polypeptide and a carrier also are not supported by a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8, 9 and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 24 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, a nucleotide sequence of SEQ ID NO: 1 and 3, does not reasonably provide enablement for nucleic acid sequences which are completely complementary to the above nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the

existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims read on nucleic acid sequences which are completely complementary to a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, a nucleotide sequence of SEQ ID NO: 1 and 3. However, other than a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, a nucleotide sequence of SEQ ID NO: 1 and 3, the specification as filed fails to disclose any other nucleotide sequences which are capable of producing the polypeptide.

Despite knowledge in the art for producing polypeptides, the specification fails to provide any guidance regarding the proteins produced by the contemplated complementary strand nucleotides and yet retain the function is lacking. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. Therefore, predicting which complementary strand generated polypeptide, if any, would retain the functions of the protein is well outside the realm of routine experimentation. Thus, an undue amount of experimentation would be required to generate the changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicants have not taught how one of skill in the art would use the full scope of polypeptide sequences encompassed by the invention of claims 24 and 28. The

specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claims 24 and 28 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claim 29 is rejected insofar as it depends on claim 28.

9. No claims are allowable but are apparently free of prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
September 12, 2002

JEFFREY STUCKER
PRIMARY EXAMINER